IRB

| | |
|---|---|
| **IRB Number:** | 20090751 |
| **Title:** | Miami Healthy Heart Initiative |
| **Principal Investigator:** | Olveen Carrasquillo (General Medicine, Division of) |
| **Printed on:** | 8/18/2014 2:27:56 PM |

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# 1. General Information

1.1. * **Title of Study/Project:**
Miami Healthy Heart Initiative

1.2. **Additional (UM/JHS/SCCC, etc.) identifying number for this study:** *(if applicable)*

1.3. * **Principal Investigator:**
Olveen Carrasquillo Professional License # (if applicable): ME104030
*NOTE: PI must be a UM Faculty. If a non-faculty member wishes to be PI of a study, approval must be received in advance from the Vice Provost of Human Subjects Research.*

1.4. **Department:** (this field will be populated automatically based on PI's department once the page is saved)
General Medicine, Division of

**Major Sub-division: (if applicable)**
General Medicine

**Research Center: (if applicable)**

1.5. **Co-Investigator(s):**

| Last Name | First Name | Employer | Department/Division | Professional Lic. # (if applicable) |
|---|---|---|---|---|
| Kenya | Sonjia | UM | General Medicine, Division of | |
| Palacio | Ana | UM | General Medicine, Division of | ME 93379 |

1.6. **Faculty Advisor(s):**

| Last Name | First Name | Employer | Department/Division | Professional Lic. # (if applicable) |
|---|---|---|---|---|

There are no items to display
*NOTE: If this is student-initiated research, a faculty advisor must be selected. If a non-faculty member wishes to be PI of a study, approval must be received in advance from the Vice Provost of Human Subjects Research.*

1.7. **Study Contact(s):**

| Last Name | First Name | Employer | Department/Division | Professional Lic. # (if applicable) |
|---|---|---|---|---|
| Alonzo | Yisel | | General Medicine, Division of | |

*NOTE: You may include as many individuals as you feel necessary to receive notifications regarding this protocol. If you do not indicate a Study Contact, only the PI will receive such notifications.*

*Note: The Principal Investigator, Co-Investigators, Faculty Advisors, and Study Contacts will have editor access to this protocol.*

1.8. **Key Study Personnel:**

| | Last Name | First Name | Employer | Role in Project | Professional Lic. # (if applicable) |
|---|---|---|---|---|---|
| View | Chang | Aileen | JHS | | TRN15499 |
| View | Cueto | Victor | JHS | | Pending |
| View | Ferras | Natalie | UM | | |
| View | Lebron | Cynthia | | | |
| View | Li | Hua | UM | | N/A |
| View | Patberg | Elizabeth | | | |
| View | Reyes-Arrechea | Ernesto | | | |

*NOTE: Individuals are considered to be "key personnel" if they have direct contact with subjects, subject data, subject records (including records-based research), protected health information or biological samples collected and/or tested for research purposes.*

- *The definition of key personnel includes individuals who may have direct responsibilities for data analysis or who contribute or collaborate in a substantive way to the scientific development of a project.*
- *Key personnel are also those listed as such on a DHHS-supported grant that is sponsoring the study.*
- *Students are considered key personnel if they meet any of these criteria.*
- *The definition of key personnel is not dependent upon whether or not the personnel receive compensation from the grant supporting the project.*
- *Pharmacists are considered key personnel and should be listed on the Form 1572 as a sub-investigator, if they will be compounding, labeling, monitoring and reporting test article compliance data.*
- *Appropriate licensure and/or certifications for study personnel are to be uploaded in section 19.6.*

1.9. * **Will this study be conducted in collaboration with a non-UM or non-JHS faculty or staff member?**

○ ○ Yes ⊙ ⊙ **No**

1.9.A. **If *yes*, list all non-UM/JHS collaborators:**

| Name | Institution | Telephone |
|---|---|---|
| There are no items to display | | |

1.10. * **Type of Research:**

Social/Behavioral

1.11. * **Type of Review Requested:**

| Select one | | Notes |
|---|---|---|
| ⊙ | Expedited Review | Study involves no more than minimal risk to human subjects and fits under one or more of the nine categories for expedited review. See UM IRB policy 8.2. |
| ○ | Exempt Review | Study involves very little, if any, risk to human subjects and fits within an exempt category listed under 45 CFR 46.101(b)(1)-(6). See UM IRB policy 8.1. |
| ○ | Full Board Review | Study does not meet the criteria for exemption or for expedited review. See UM IRB policy 8.3. |
| ○ | Emergency | See UM IRB policy 27.1. |

| | |
|---|---|
| ○ Use | |
| ○ Facilitated Review | Study reviewed and approved by **NCI-CIRB/Pediatric CIRB**. |
| ○ External IRB Review | Requesting review by external IRB (e.g. **Florida Department of Health IRB**). |

*NOTE: For a summary describing the types of review, please see IRB Review and Approval Process and Instructions for Review Categories.*

**1.11.A. If** *External IRB Review*, **select the proposed IRB of record for this study:**

## 1a. Expedited Review Categories

*Applicability for Expedited Review:*

- Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- The categories in this list apply regardless of the age of subjects, except as noted.
- The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The expedited review procedure may not be used for classified research involving human subjects.

1.11.A. * **Under what category is expedited review being requested?** *Please check all that apply:*

| Category | Description |
|---|---|
| **2** | Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:<br><br>**(a)** From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or<br><br>**(b)** From other adults and children, considering the age, weight, and health of subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.<br>Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications) Examples: |

| | |
|---|---|
| **4** | **(a)** physical sensors that are applied either to the surface of the body or at a distance and do not involve input or significant amounts of energy into the subject or an invasion of the subject's privacy;<br><br>**(b)** weighing or testing sensory acuity;<br><br>**(c)** magnetic resonance imaging;<br><br>**(d)** electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;<br><br>**(e)** moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. |
| **7** | Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt) |

## 1c. General Information (cont'd)

1.12. * **Proposed Start Date:**
11/2/2009

1.13. **Anticipated Completion Date:**
☐☐ **Check here if completion date is uncertain**

*CRIS*

To determine whether the UM CRIS Office (Clinical Research Initiation Service) must complete a Medicare Coverage Analysis (MCA) and/or a contract for this Study, please answer the following:

1.14 * **Study Involves:**
Study Involves

- ○ Chart review **only**
- ○ Interview or survey activities **only**
- ○ Limited data set **only**
- ○ Observational **only**
- ◉ Testing a drug, device, or biologic, or performing procedures, lab tests (including blood draws) and/or interventions (standard of care and/or experimental)
- ○ None of the above

1.15 * **Type of Study:**

| Check all that apply | Description |
|---|---|
| ☑ Prospective | Collecting new data |
| ☑ | |
| ☐ Retrospective | Looking only at data already collected |

1.16 * **Who initiated this study?**
Investigator-initiated

1.17 * **Will you use the University of Miami's Velos eResearch system to track this study, its subjects, milestones, and/or related data collection?**
◉ ◉ **Yes** ○ ○ No

If *yes*, the Velos eResearch system will be notified for your protocol. See http://med.miami.edu/orim for additional information on Velos.

1.17.A. **If *yes*, will you require assistance to develop electronic versions of your finalized case report forms for data collection within Velos eResearch?**
◉ ◉ **Yes** ○ ○ No

If *yes*, notification will be sent to the Office of Research Information Management (ORIM) regarding the need for follow-up. It is recommended to discuss this with ORIM as early as possible in the CRF development process.

NOTE: If Study involves testing a drug, device, or biologic, and/or if procedures, lab tests and/or interventions will be performed on a patient as part of the Study:

1. A coverage determination and/or contract are likely required from CRIS.
2. The study must comply with the UM's patient enrollment and tracking policy. UM's Clinical Research Revenue Cycle (CRRC) office must be notified of a consented subject no later than 24 hours after receiving a signed consent (including screening consents) and upon patient disenrollment. Notification can be submitted to CRRC automatically via Velos or manually via the CRIS website (http://med.miami.edu/cris)
3. eProst will notify the CRIS Office about this Study. The Study may not be initiated until CRIS and the IRB approve it.

## 1e. Methods & Procedures - Social/Behavioral

1.19. * **Methods & Procedures:**
Check all that apply
Changes in diet or exercise
Interviews, surveys, questionnaires
Venipuncture, blood drawing, etc.
Vulnerable populations

1.19.A. **If *Other*, please specify and explain:**

1.20. * **Are there any medical procedures not checked above involved in this study?**
○ ○ Yes ◉ ◉ **No**

1.20.A. **If *yes*, please explain:**

## 2. Supplemental Study Information - All Studies

2.1. * **Will human biological samples be used in this research?**
◉ ◉ **Yes** ○ ○ No

2.2. * **Does the study involve genetic testing of subjects or their samples?**
○ ○ Yes ◉ ◉ **No**

2.3. * **Does this study involve cancer patients, diagnosis, therapy, or prevention?**
○ ○ Yes ◉ ◉ **No**

*NOTE: Approval from the Cancer Protocol Review Committee is required for all studies involving cancer patients, diagnosis, or therapy.*

## 2b. Ancillary Committee Approval Requirements

**Does this research involve:**

* 2.8. **facilities and/or support from the Clinical Research Center?** (if yes, approval from the CRC is required)
◉ ◉ **Yes**
○ ○ No

* 2.9. **biological agents, Biosafety Level 2 (BSL2) and higher, including, but not limited to, infectious and potentially infectious agents?** (if yes, approval from the Office of Environmental Health and Safety, Biosafety officer, is required. See EHS website for the Biological Agents registration form)
◉ ◉ **Yes**
○ ○ No

2.9.A. If *yes*, upload the biological agents registration form:

| Name | Version |
|---|---|
| BiologicalAgentRegistrationForm.pdf | 0.01 |

* 2.10. **patient specimen collected at any UM/JHS patient care facility, archived tissues or slides, and/or Department of Pathology expertise or facilities?** (if yes, approval from the Pathology Research Steering Committee is required. See HSRO website for additional information.)
○ ○ Yes
◉ ◉ **No**

* 2.11. **radioactive materials, radioisotopes, and/or radiation producing equipment** (if yes, approval from the Radiation Safety Office is required. See HSRO website for additional information.)
○ ○ Yes
◉ ◉ **No**

* 2.12. **prospective interventions with participants who have cancer?** (if yes, approval from the Protocol Review Committee is required. See PRC website for additional information.)
○ ○

Yes
**No**

2.12.A. If *yes*, upload approval documentation if this study has already been approved by the Protocol Review Committee:

| name | version |
|---|---|
| There are no items to display | |

## 3. Research Location(s)

3.1. * **Is this a multi-center study?** (A multi-center study is one in which non-UM PIs at different institutions are conducting the same study.)
Yes **No**

3.1.A. **If *yes*, is the University of Miami the coordinating center?**
Yes No

3.2. * **List all Performance Sites "engaged" in this research.**
*NOTE: For multi-center studies, list performance sites only for the research being conducted by the UM principal investigator. Even if UM is the only site, it must be indicated here.*

*An institution or performance site is "engaged in this research" when its employees or agents (i) intervene or interact with living individuals for these research purposes; (ii) obtain individually identifiable private information for these research purposes; or (iii) if the institution receives a direct federal award to support this research. This may apply when a UM investigator collaborates with a non-UM investigator or institution, or when UM serves as a Coordinating Center. Each PI at each non-UM performance site will require a letter of IRB approval from the site's IRB. If the site has an FWA, list below. See OHRP guidance at http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm. Also see UM IRB "Subcontracts for Non-UM Institutions or Individuals 'Engaged' in UM Research."*

| Name of Performance Site | If Other, Site Name | IRB Approval |
|---|---|---|
| University of Miami | | |
| Jackson Health Systems | | |

3.3. * **Are there any performance sites "involved" but NOT "engaged" in this research?**
Yes **No**

*NOTE: If a UM investigator will be conducting research at a non-UM site or institution (e.g. when only recruiting subjects, collecting specimens, etc. at the site) and the employees or agents of the institution or performance site (i) do not intervene or interact with living individuals for these research purposes; or (ii) do not obtain individually identifiable private information for these research purposes; or (iii) if the institution does not receive a direct federal award to support this research, THEN the institution or performance site is considered "involved" but not "engaged" in the research. See UM IRB Policy "Agreement for Non-UM Institutions or Individuals 'Involved' in UM Research."*

3.3.A. **If *yes*, list all Performance Site(s) "involved" but NOT "engaged" in this research:**

| Name of Performance Site | IRB Approval Letter | Letter of Cooperation |
|---|---|---|
| There are no items to display | | |

3.4. * **Will you be conducting this study at any institutions other than UM or JHS?**
○ ○Yes ⊙ ⊙**No**

3.4.A. **If *yes*, a copy of the institution's IRB approval must be attached:**

| Name | Description | Version |
|---|---|---|
| There are no items to display | | |

3.5. *** Does this study involve UM related research activities conducted or coordinated at one or more sites outside of the United States?**
○ ○**Yes** ⊙ ⊙**No**

## 3b. Other UM or Jackson Health System Protocols & JHS Activities

3.6. * **Is this research part of a larger grant that includes other UM or Jackson Health System protocols?**
○ ○Yes ⊙ ⊙**No**

3.6.A. **If *yes*, please define Protocol(s) by ID, title, and Principal Investigator:**

| Protocol ID | Title | Principal Investigator |
|---|---|---|
| There are no items to display | | |

3.7. * **Are any study-related activities performed at a JHS site?**
⊙ ⊙**Yes** ○ ○No

## 3c. Jackson Health Systems

3.7.A. * **The activities performed at Jackson Health Systems consist of:**
Check all that apply
☑ Recruitment of subjects
☑
☐ Facilities use
☐
☐ Retrospective analysis of charts/records
☐
☐ Subject interventions such as tests, measurements, drug administration, surgery, consenting
☐ subjects, etc.

3.7.B. * **List all Jackson Health System sites involved in this research:**

| Check All That Apply | Group |
|---|---|
| Jackson Memorial Hospital | JHS-1 JHS Hospitals |

3.7.B.(i) **If *other* in 3.7.B, please specify:**

3.8. * **Does the study require use of Jackson resources?**
○ ○Yes ⊙ ⊙**No**

3.8.A. **If *yes*, describe activities requiring use of Jackson resources:**

3.9. * **Will the Jackson Health System incur any expenses as a result of this research?**
○ ○ Yes ⊙ ⊙ **No**

3.9.A. **If *yes*, please indicate the type of expense(s) that the Jackson Health System will incur:**

| Type of Expense | Estimated Amount |
|---|---|
| There are no items to display | |

3.10. * **Will the Jackson Comprehensive Treatment Unit (JHS CTU) nurses perform study-related procedures as required for the conduct of the study?**
○ ○ Yes ⊙ ⊙ **No**

3.11. * **Upload completed and signed JHS CRRC forms:**

| Name | Description | Version |
|---|---|---|
| JHS CRRC form | | 0.01 |

*NOTE: The Jackson Clinical Trials Office Application Form is available from the Jackson Clinical Research Review Committee page.*

# 4. Description of Study

*Study Protocol*

4.1. * **Abstract and Specific Aims**
**Include a brief summary of the significance, purpose or research question, specific aims, and risks/benefits. Specific aims include hypotheses you will investigate.**
SPECIFIC AIMS of the Miami Healthy Heart Initiative (MHHI).

Disparities in the epidemiology of cardiovascular disease (CVD) risk factors among Latinos have been extensively described; however, traditional medical models of CVD risk reduction have not been very effective in Latinos. One promising strategy is the use of community-based community health workers (CHWs). CHWs have long been used in Latin-America as an integral part of their health care delivery system. Further, preliminary data from our prior pilot diabetes self-management CHW program have shown improvements in lipids. However, because of a lack of effectiveness data from studies using rigorous experimental designs, the adoption of the CHW model has been quite limited both locally and nationally. In MHHI, our goal is to examine the effectiveness of a CHW intervention in CVD risk reduction among Latinos.
We propose to examine the effectiveness of a multilevel CHW intervention as an adjunct to routine primary care in reducing CVD risk factors among diabetic Latinos Miami. The UM Jay Weiss Center which has substantial experience in Community Health Worker Program will take the lead role in the development and implementation intervention of the CHW program.

The study design is a randomized controlled trial (RCT) of 300 Latino patients age 35-65 with poorly controlled diabetes (AIC >=8.0) followed at the Ambulatory Care Clinic (ACC) of Jackson Memorial Hospital (JMH).

Primary Objective: To determine if the CHW intervention results in lowering of CVD risk factors including blood pressure, LDL cholesterol, and diabetes control (AIC). as measured by the Total Framingham Risk Score (FRS); the primary outcome.

Secondary Objectives: To determine if the CHW intervention results in improvements in the following putative mechanisms that may influence the FRS:
a. Medication adherence (measured by validated instruments)
b. Improvements in diet and exercise (as measured by validated instruments);

Hypotheses: Among patients receiving care at the ACC we hypothesize that as compared to those in

enhanced usual care, patients randomized to the CHW intervention at 18 months will have:
a. Greater reductions in blood pressure and low density lipoprotein (LDL)
b. Improved glycemic control
c. Greater rates of medication adherence (taking >80% of specified medication doses)
d. Increases in physical activity (kcal/week)
e. Increases in mean number of daily vegetables consumed

4.2. * **Research Background**
**Provide background and previous studies supporting the study rationale. Include a brief summary of existing knowledge relevant to the research. Explain how the research may contribute to the advancement of knowledge.**
B1. Burden of cardiovascular disease among Hispanics

A major goal in Healthy people 2010 was to "Improve cardiovascular health and quality of life through the prevention, detection, and treatment of CVD risk factors".23 Although CVD mortality is lower among Hispanics than non-Hispanics whites (NHWs), CVD remains the leading cause of death for Latinos, accounting for 24% of all deaths.24-27 Latinos have the highest prevalence of metabolic syndrome of any ethnic/racial group28 and typically have a less favorable CHD risk profile than NHWs26, 29-32 Diabetes in particular is prominent among all Latinos subgroups, with prevalence rates twice as high as those of NHWs.33 Hispanics also have a higher prevalence of obesity than NHWs.34 The prevalence of hypertension (HTN) is similar in Latinos and non-Hispanic whites.35 However, Latinos are less likely to have the condition diagnosed, and less likely to be controlled than NHWs.36, 37 Latinos are also less likely to be screened or receive treatment for high cholesterol.38,39 Studies also suggest that Caribbean Latinos may have a higher prevalence and incidence of vascular disease than NHWs, a pattern quite distinct from that in non-Caribbean Latinos.21, 40 Similarly, unlike white Latinos, those of Afro-Caribbean descent may also be at increased risk of hypertension than NHWs.22

B2. Need for effective interventions that can address racial and ethnic disparities.

A large body of literature documents the persistence of racial and ethnic disparities in health care,46, 47 a condition that Healthy People 201023 is intended to address. Thus, there is increased interest within health institutions and funders on research to improve the health of disadvantaged populations through collaborations between researchers and communities affected by such disparities.48 CBPR is a collaborative approach to research meant to increase the efficacy and effectiveness of studies for both researchers and representatives of the community being studied.49 The Agency for Health Care Research and Quality's (AHRQ) has found CBPR particularly useful in addressing disparities and concluded that when done properly, CBPR benefits the community, health care practitioners, and researchers alike.50 CBPR was also recently identified as one of six strategic imperatives by the Centers for Disease Control (CDC) to eliminate CVD disparities.51

Rationale for Community Partnerships for CVD Interventions in Latino Communities

Latinos remain inadequately targeted for CVD risk factors reduction strategies.26 Further, traditional medical models of CVD risk reduction have not been very effective in Hispanics.52, 53 One reason, is that the barriers mediating disparities, including lack of insurance, barriers due to Medicaid coverage, cultural competence, language, trust in the health system, competing demands (work/ child care) and limited neighborhood access to healthy lifestyles (diet/exercise) are more difficult to address with traditional medical models.27

Initiatives among Latinos. To date there have been few organized community programs to lower CVD risk that specifically target Latinos and also include a rigorous evaluation component. Examples include the Stanford Heart Disease Program,12 the Sand Diego Family study16 and Project SALSA in Southern California.54 Another comprehensive approach to CVD risk reduction is the NHLBI's Latino Community Cardiovascular Disease Prevention & Outreach Initiative.10 Launched in 1994 and now known as Salud para su Corazón, it was pilot-tested in Washington DC and is now active in several Southwestern states.10 In this application we propose to use materials developed under that initiative including A

Guide for Building Community Programs55 and their Lay Health Worker Training Manual.56 Since then the NHLBI has funded 12 community based education projects through a network of Enhanced Dissemination and Utilization Centers (EDUCs),57including one in Texas focused on Latinos.58, 59 In section B.3 we summarize some of these community based programs. One of the most important lessons was that effective CVD interventions require active partnerships with the community and the programs must be tailored to the local Latino culture.27

B3. Rationale for Community Health Workers.
What are CHWs. CHWs are community members without formal health care education who serve as a link between patients and providers.60 CHWs are often referred to by various terms, including outreach worker, lay health advisors, promotoras, and patient navigators.61, 62 The National Community Health Advisory Study63 identified core services provided by CHWs: to serve as links between communities and health care systems, act as patient and community advocates, provide disease prevention/health promotion education, provide social support and counseling, build individual and community capacity, assure receipt of services and provide direct health services. CHWs are qualified to provide these services because they are members of the community they serve, understand local health beliefs, are versed in community health, communicate in the language of the community and understand the social and historical experiences shaping their communities.
CHWs have been shown to be effective in other groups. In the US, CHWs have been part of outreach programs since the 1960's. Numerous studies have also shown that CHWs can produce a wide range of benefits, including increased access to care,60, 62, 64 decreased hospitalization,65 and increased use of preventive services.66 Among blacks, CHWs have been shown to improve blood pressure,67 increase exercise,65 and improve glycemic control.68 Most recently, Becker et. al.69 used a community-based multiple risk factor intervention which included CHWs in a randomized controlled trial (RCT) of blacks in Maryland and showed a 25% reduction in Framingham risk factor scores versus 3% in the control group. Unlike our proposed study, that intervention used a nurse practitioner as a case manager in delivering care that was independent of primary care. Our proposal does not involve case management.

Effectiveness of CHWs for CVD in Latino communities remains unclear. In the Hispanic community, CHWs have been shown to improve self-care practices and knowledge among diabetics.70, 71 Improvements in knowledge and behaviors aimed at CVD risk factors have also been reported.10, 11 Self-management groups led by CHWs improved health status, health behavior, and self-efficacy among patients with chronic conditions.72 However, there is still a dearth of evaluation literature on CHWs and very limited evidence from RCTs on the impact of CHWs on most health outcomes.6 The reason is for this is because while most CHWs program maintain adequate records to produce descriptive data such as number of clients seen, the types of problems the clients had, and what actions the CHWs took, they generally do not collect outcome data.62 In particular, data on cardiovascular risk factors are extremely limited. Excluding glycemic control, our review of the literature identified only 6 peer reviewed articles with a rigorous evaluation design examining the impact of CHW interventions among Latinos on CVD.

Author
Study design
Intervention
Outcomes

Alcalay10
Pre-post test design
Multimedia intervention that included promotoras
Improved CVD knowledge

Balcazar11
Pre-post test design
Improve CHW skills
Improved CHW CVD knowledge and performance skills

Giachello14

Pre-post test design
Integrated multilevel including classes and programs designed by CHWs12 mg/dl reduction in cholesterol

Farquhar12
Cities were randomized
5-year multi-channel multifactor education using CHWs
Reductions in cholesterol (2%), BP (4%), and smoking (13%)

Nader16
Families were randomized
Nutrition/ exercise including educational sessions by CHWs
Improved eating habits, 2 mmHg reductions in BP

Staten17, 73
Persons were randomized
Provider counseling, health education, +/- CHW support
Increases in number of fruits and vegetables in CHW group.

Only three of these studies involved a randomized design and few evaluated medical risk factors for CVD such as cholesterol and blood pressure, and none used a comprehensive CVD prediction model. Further, all were on Latinos of Mexican origin. In summary, randomized control studies evaluating CHW interventions on CVD among non-Mexican Latinos remain as a gap in the peer reviewed literature.

Underutlization and Limited Dissemination of CHWs. Although the federal government first endorsed the use of CHWs in the 1960s, outside of grant funded programs, CHWs remain extremely underutilized. While lack of understanding of the CHW concept may play a role, the dearth of evaluation literature on CHWs is the primary culprit that has limited their application.6 In reviewing the evidence base for CHWs, the Task Force on Community Preventive Services concluded "due to conflicting and limited results, few high quality studies, and small sample sizes there is still insufficient evidence to determine the effectiveness of CHWs interventions".8 The Office of Minority Health's review also reached a similar conclusion.7 The Cochrane database systematic review of lay health workers and CVD concludes "evidence of the effectiveness of LHW interventions is so far insufficient to allow recommendations for policy and practice."9

4.3. **If you have cited references above, please attach a bibliography, including title, full author list, journal, date and pages. This bibliography should include only those articles referenced above.**

| Name | Description | Version |
|---|---|---|
| orbbackgroundrefs.docx | | 0.01 |

## 4a. Description of Study (cont'd)

*Rationale and Methodology*

4.4. * **In non-technical, lay language, describe the study design and all study procedures, in order of sequence and timing. Include length of subject participation, what tasks are involved in the study, what tests or procedures subjects will be asked to complete or undergo, specific measures to be used, etc. If applicable, include frequency of visits, duration of visits, and study procedure calendar.**
We propose a study of 300 patients receiving care at the Ambulatory Care Clinic (ACC) of Jackson Memorial Hospital (JMH). Patients with aged 35- 65 years with poorly controlled diabetes will be randomized to either the intervention (CHW) or to enhanced usual care (EUC) and followed for one year. Subjects will be identified during their visit to the ACC by provider referral or by review of the electronic health records.

Study procedures: All subjects will come to the CGRC to have blood drawn for their cholesterol and diabetes levels, will have their height weight and blood pressure taken and answer a series of questionnaires that will take approximately 60 minutes to complete. The same procedure will be repeated at 12 months.

Intervention Group: Community Health Worker (CHW) will be a medical and social advocate to help Latino diabetic patients manage their risk for cardiovascular disease by accessing relevant care and implementing lifestyle behaviors to reduce health risks. CHW will require to have a high school graduate or GED. Must be interested in cardiovascular health and committed to helping others access healthcare. Knowledge of central Miami communities with large Hispanic populations. Fluent in English and in Spanish oral and written. The Jay Weiss Center will provide ongoing training focusing on communications skills, interpersonal skills, informal counseling, services coordination skills, capacity-building skills, advocacy skills, technical skills, organizational skills, and healthy specialty modules.

Those subjects assigned to the CHW will continue to received their usual health care from their health care provider at the ACC. In addition, the CHW will assist them by providing assistance (when needed) with patient navigation (help making appointments getting medications refilled, helping patients communicate with their provider etc), assistance with diet and exercise (providing nutrition information, cooking classes, resources on exercise), and when needed assist patients with community resources (referrals to immigration programs, housing assistance, etc). This CHW intervention will involve at a minimum 4 or more home visits, 5 nutrition education group sessions held at the Jay Weiss Center, and 10 follow- up phone calls over a 12 month time period. All group activities will be supervised and logged by Jay Weiss Center Social Worker. All group notes will be saved in a locked file drawer as well coded and saved under Velos.
Photo and Audio Consent form is included for participants, study plans to have special events and trainings with participants. Photos and Audio maybe used for health fairs, educational support groups, nutrition classes, diabetes trainings. Photos may be used for the Jay Weiss Center newsletters, flyers, and brochures.

Enhanced Usual Care: Those who are not randomized to the CHW will also continue with their usual care by their ACC provider. They will also receive by mail several brochures on things they can do to maintain healthy including NIH materials on diabetes and healthy heart activities.
The brochures will be mailed out every 4 months. Subjects will recieve a Spanish or English booklet (based on patient preference) on diabetes care. This will be the National Diabetes Education Program's (NDEP) "7 Principles for Controlling Your Diabetes for Life", a 20-page booklet providing basic and easy to read information on diabetes control and diabetes care which is available in Spanish. The second is the NDEP bilingual meal planner which includes dietary tips and recipes to help control diabetes. The other is an NHLBI biligual Latino recipe cookbook. The forth is a NIH booklet "Conversando con su Medico", provides advice guidance, effective tips and strategies for Latino patients to better communicate with their physician.

In addition, we propose to examine 50 randomly selected participants with poor glycemic control and measure bone and mineral metabolism with our existing blood samples. Prior small studies showed differences in these parameters by diabetes status, but no study looked at all of these parameters jointly. Poor glycemic control has multiple adverse consequences that our study affords the opportunity to assess. To do this, we will measure 1) sclerostin; 2)c- terminal FGF23, 3) intact PTH, and 4)serum creatinine in stored deidentified baseline samples from 50 participants. One serum and one plasma aliquot for the 50 participants will be analyzed which are already stored in the Clinical Research Center. No protected health information will be used: all data acquisition, storage, analysis and presentation will be performed without use of identifiers or protected health information.

In addition to the 8cc needed to process the AIC and LDL all subjects will be asked to have an additional 14 cc of blood drwan and saved in a repository for future research studies for 5 years from time of blood draw.
A link will be maintained to each individual subject. The study sepcific linkage file will be maintained separately from all other study data.

4.4.A. **Standard Measures:** Click the "Add" button to open the search window, then click the "Find" button to browse and select measures.

| Name of Measure | Brief Description | Type of Measure |
|---|---|---|
| There are no items to display | | |

NOTE: A copy of the first page of each standard measure is provided in the Library of Standard Measures for verification. Ensure that the version being used in this study is the same as the version that has been selected.

**Upload any questionnaires and/or assessment tools to be used that are not listed above:**

| Name | Description | Version |
|---|---|---|
| 20090751_LTR_IRBapp_Pre_postlabresults_ENG | | 0.01 |
| 20090751_LTR_IRBapp_Pre_postlabresults_SPN | | 0.01 |
| 20090751_NFO_LabResultsLetter_IRBApp112110_ENG&SPA.doc | | 0.01 |
| 20090751_QUE_IRBApp_Baseline_ENG.doc | | 0.07 |
| 20090751_QUE_IRBApp_Baseline_SPN.doc | | 0.08 |
| 20090751_QUE_IRBApp_ExitIntervention_ENG.doc | | 0.01 |
| 20090751_QUE_IRBApp_ExitIntervention_SPN.doc | | 0.01 |
| 20090751_QUE_IRBApp_ExitInterview_ENG.doc | | 0.04 |
| 20090751_QUE_IRBApp_ExitInterview_SPN.doc | | 0.03 |
| 20090751_QUE_IRBApp_IntakeForm_ENG.doc | | 0.07 |
| 20090751_QUE_IRBApp_IntakeForm_SPN.doc | | 0.04 |
| Spanish Cert LTP 2013.pdf | | 0.01 |

4.5. **Identify and distinguish between those procedures that are standard treatment versus those that are experimental/research-specific.**

☐☐ **Not applicable**

All patients will continue to receive their standard medical care from their health care provider at the ACC. However, the reserach specific procedures include:
a) the initial and 12 month GCRC visit where patients will have their blood drawn for cholesterol and AIC, their weight and blood pressure taken and answer a series of questions that should take about 60 minutes to complete.
b) for those randomized to the CHW intrevention, the home visits, group classes, and phone calls.
c) for those randomized to enhanced usual care- the health information borchures that will be mailed.

4.6. **Describe any therapeutic alternatives that may exist for the study population.**

☐☐ **Not applicable**

Patients may choose not to participate in the study and instead simply continue their usual care by their provider at the ACC.

## 4b. Description of Study (cont'd)

*Risk/Benefit Assessment*

4.7. * **Describe the nature, degree, and if available, expected frequency of all potential economic/financial, legal, physical, psychological, social or other risks to which research participants may be exposed as a result of their participation in this research. If applicable, please describe the risk of investigational agents or devices (side effects).**

1. The largest risk would be that blood drawing may result in some bruising of the skin, some bleeding or swelling at the site of blood draw.
2. Potential breach of patient privacy/ confidentiality

4.8. * **Are there potential direct benefits of this research to the subjects?**
⦿ ⦿ **Yes** ○ ○ No

4.8.A. **If *yes*, provide a description of the potential direct benefits and indicate if all, or only some, of the subject groups may derive this potential benefit.**
1. There may be direct benefits to the participants in the intervention condition in terms of hypothesized reductions in blood pressure, cholestrol and AIC.

2. Control group subjects would receive a series of NHLBI approved publications on CVD risk factor reduction strategies.

4.9. * **Are there potential benefits of this research to society?**
⦿ ⦿ **Yes** ○ ○ No

4.9.A. * **Please explain:**
Studies proving the effectiveness of CHW may lead to increased dissemination of this health care strategy. Payors such as insurance companies may also see the value of reimbursing for the services of CHWs to improve care of Latino diabetic patients.

4.10. * **Explain why the risk/benefit ratio supports conducting this research.**
1. To minimize the risk of blood drawing all blood draws will be performed by certified phlebotomists, under standard conditions and with appropriate medical attention to address any emergency that may arise from the blood draws.

2. Data confidentiality: All participants will be reminded that their responses are confidential, that appropriate methods are being taken to protect their confidentiality and that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such an action will in no way affect their future interactions with their health care provider. To ensure confidentiality, data will be associated with an individual participant only by an assigned identification number, the code for which will be kept in a locked drawer.

Given that these risks are minor and large potential to improve the patients cardiovascular risk factors ad well as larger benefits to society we feel the benefits outweigh the proposed risks.

## 4c. Description of Study (cont'd)

*Data*

4.11. * **Describe follow-up, data storage methods, data security, authorized access to records and record retention, including site name and address.**
All of data for the proposed study will be collected, entered, stored and retained electronically using UM's VELOS system.

The procedures for data storage, data security, authorized access and record retention, including site name and address are described at: http://www.med.miami.edu/orim/x14.xml

The PI will designate user access to VELOS for study team members.

While all attempts will be made to assure that all data is collected electronic in cases where hard copies of materials are required by UM(such as a patient's signed informed consent forms), these will be kept under lock and key in Dr. Carrasquillo's office at the CRB (in locked file cabinet in a locked office ).

4.12. * **Support the study validity by describing the statistical design, including quantitative and qualitative methods used to analyze data.**
D14. Statistical Analysis.

The following section describes analytic strategies and power calculations performed to determine

sample size. These calculations assume specific analytic strategies which are likely to be among those adopted.

Design: Once screened and evaluated at baseline, the basic study design consists of simple random assignment of individuals to one of two treatment arms: CHW or enhanced usual care. Because there will be clustering by primary care provider (PCP), with each PCP contributing patients, randomization will be stratified by PCP. Data will be collected at two points in time (baseline and 12 month follow-up).

Attrition: It is anticipated that attrition will be primarily due to drop-out (mortality will be rare in this age group). Other types of missing data, such as unanswered questions will be handled by pro-rating algorithms. Assumptions about attrition are based on the experience in IDEATel. In that study (an older cohort, the majority 65 and over) the downstate 12 month attrition (including dropout and mortality) was about 12%; at 24 months of follow-up, the attrition was 20%. Given that the proposed sample will be under the age of 65, and only followed for 12 months, a conservative estimate of attrition will be 20%; however, a very conservative rate of 30% was used in some power calculations. Intent-to-treat is the analytic strategy proposed, and all subjects will be encouraged to return for the follow-up interview even if they were randomized to the CHW group but did not complete the 12 month intervention.

Unit of analysis and clustering: The patient will constitute the unit of analysis for the study. Patients will be randomized within PCP; therefore, sample sizes must be larger to account for unreliability of measures and for design features. Both correlation among repeated measures over time on the same subject and correlation due to clustering of patients within providers (characteristics of the providers or practice which may influence outcomes among their patients) will be taken into account. This dependency among members of the cluster will inflate the variance of the effect of the intervention.

Adjustment for Multiple Comparisons: Adjustment for multiple comparisons is an area of controversy. Following recent guidelines for clinical trials, we propose to treat primary and secondary outcomes as separate clusters, setting a .05 level of significance to the primary outcomes within each cluster. A Bonferroni correction would then be applied to secondary treatment mediator outcomes. Thus, a .05 level will be assigned to the LDL, SBP, and HgA1C coutcomes, and a .01 level to the three secondary outcomes (medication adherence, diet, exercise).

Analyses: A parallel group design with equivalent baseline values as a result of randomization is proposed. Because the design is to randomize individuals to groups within PCP strata, some baseline imbalance in the outcome might occur; in this case the basic analytic approach will be an ANCOVA model that adjusts for baseline values of the outcome, as well as for the design feature of clustering. In order to determine the best approach, two basic models could be examined. One is a basic t-test or ANCOVA approach, with inclusion of a random effect for PCP to model the clustered data. The second is a repeated measures approach that examines time as continuous. The latter allows inclusion of more subjects, however, with only two waves of data (and if 90% of the subjects are interviewed within plus or minus two months of the 12 month mark), it is not clear that there will be sufficient benefits associated with the approach. The post-treatment values of continuous outcomes will be modeled as functions of baseline values, treatment and the interaction of baseline and treatment. A general longitudinal mixed effects model, using SAS PROC MIXED will be used to allow for the correlation between subjects within a PCP. Additionally, the group heterogeneity in cluster and residual variances may require modeling in order to satisfy model assumptions and improve model fit. (There may be violations of the more rigid assumptions involved in ANCOVA, for example homoscedasticity, so that modeling the group heterogeneity in cluster and residual variances will be necessary.) Based on prior analytic experience with the outcome variables we do not anticipate the need to transform them.

Although our primary analysis is to examine LDL, SBP and HgA1c as continuous measures, we also propose to examine it these as binary outcome . In this case, such dichotomous outcome measures will be analyzed using generalized estimating equations (GEE) to account for potentially correlated outcomes of subjects with the same PCP (PROC GLIMMIX in SAS).

Prior to analyses, baseline values of all variables from each arm will be examined; however, no p values will be provided, and covariates (other than baseline values) are not proposed for inclusion in the main analyses of treatment effects. Examination of baseline differences on key variables between subjects lost-to-follow-up will also be conducted (e.g. gender). The first set of analyses will not adjust for dropout. Only cases with complete data will be included; however, as stated, these analyses will include those who did not complete the CHW intervention but who returned to provide the follow-up interview, under an intent-to-treat design. The intent-to-treat analyses of the total group will later be repeated using baseline values carried forward to account for cases lost to follow-up (using SAS PROC MIXED). However, baseline values carried over may not always be the best method, depending on the type of variable studied. For example, blood pressure may get worse over time due to aging. Thus, other methods of examining missing data, e.g., propensity scores, EM algorithm and multiple imputation sensitivity analyses will be considered.

Power Analyses:
LDL: Data from the IDEATel study were used for estimation; the pooled mean and standard deviation for the sample among those with A1c >= 8 was 106.10 and 32.90, respectively at baseline. (The experimental group means and standard deviations at baseline, and one year follow-up were 107.28 (32.93) and 99.31 (33.66) respectively; while the comparable values for the control group were 104.84 (32.94) and 110.28 (41.37). The following is assumed: $\alpha = .01$; $1-\beta = .80$ $\delta=\mu1-\mu2 = 13.8$ units (the adjusted differences were 12 units); $\sigma2 = (32.90)2$; R (reliability) = .90; r (intracluster correlation) = .03; g (average cluster size) = 2.5. Given this scenario, an effect size of 12.8 points can be detected, with power >.95.

Blood pressure: (SBP) Using data from IDEATel, with the same assumptions as above, even with attrition of 30% a 11.8 point difference in systolic blood pressure and 5.3 point difference in diastolic blood pressure could be detected.

AIC: Data from the IDEATel study were used for estimation; the pooled mean and standard deviation for the with group an HgA1c greater than or equal to eight percent, was 9.53 and 1.36, respectively at baseline.

These calculations apply to two parallel groups and assume less than perfect reliability of change scores. We assume the following: $\alpha = .05$; $1-\beta = .80$ $\delta=\mu1-\mu2 = 0.51$ units; $\sigma2 = (1.36)2$; R (reliability) = .90; r (intracluster correlation) = .03; g (average cluster size) = 2.5.
$n^* = [2(\sigma2T + \sigma2e)(Z\alpha/2 + Z\beta)2]/\delta2$, adjusting for unreliability: $n=n^*/R$ (See Fleiss pp4-5) and $n^*=102$; n=108/group; adjusting for clustering, using the variance inflation factor, $IF = 1 + (g-1)r = 1.05$, the adjusted n = 119/group; after (30%) attrition, with n=170, an effect size as small as 0.51 could be detected.
If all subjects are included in the analyses, smaller effect sizes can be detected, however, expected group differences would be smaller given baseline carried forward. Thus, 150 subjects per group is a sufficient sample size for the detection of an effect size as small as a change of 0.5 in HgA1C. Such a decrease is considered clinically meaningful and represents about a 5% decrease in relative risk for development of microvascular complictaions. As noted previously, in our pilot study of 31 patients enrolled in Alianza's diabetes CHW programs, a pre-post test difference in of 1.3 was observed.

*Privacy/Confidentiality Agreements*

4.13. **Describe any privacy agreements or certificates of confidentiality, if applicable.**

## 4d. Description of Study (cont'd)

*Deception*

4.14. *** Is the use of deception part of the study design?**
○ ○ **Yes** ⊙ ⊙ **No**

**If *yes*, please answer the following 3 questions:**

4.14.A. **Describe in detail the nature of the deception and explain why this is necessary for the research.**

4.14.B. **State how, when, and by whom the research subjects will be debriefed.**

4.14.C. **Upload a copy of the debriefing script.**

## 5. Study Participants

Per 45 CFR 46, human subjects (participants) means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual; or
2. identifiable private information (i.e. pathological specimens, medical records, etc.)

5.1. * **Participant Age:**

| Check all that apply | | Notes |
|---|---|---|
| ☐ | 0-6 | *Parent Permission/Consent required for each participant* |
| ☐ | 7-17 | *Parent Permission/Consent & Child Assent required for each participant* |
| ☑ | 18-65 | *Consent required for each participant unless a waiver of consent is approved by the IRB* |
| ☑ | 65+ | *Consent required for each participant unless a waiver of consent is approved by the IRB* |

5.2. **For the following questions, please use integers for your responses. For any question that is not applicable, please enter the number *0*.**
**(Do not enter commas, decimal points or special characters)**

5.2.A. * **Maximum number of subjects in the Protocol to be *screened* at all sites (regardless of PI):**
800

5.2.B. * **Total number of subjects in the Protocol to be *studied* at all sites(regardless of PI):**

300

*University of Miami*

5.2.C. * **Maximum number of subjects to be *screened* by this PI at *UM*:**
0

* **Maximum number of subjects to be *enrolled* by this PI *at UM*:**
0

* **From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment?**
0

*Jackson Health Systems*

5.2.D. * **Maximum number of subjects to be *screened* by this PI at *Jackson Health Systems (JHS):***
800

* **Maximum number of subjects to be *enrolled* by this PI *at Jackson Health Systems***

*(JHS)*:
300

* **From the above, how many are expected to** *complete* **this study (participate in the study beyond initial enrollment)?**
300

*Miami VA Medical Center*

5.2.E. * **Maximum number of subjects to be** *screened* **by this PI at** *Miami VA Medical Center*:
0

* **Maximum number of subjects to be** *enrolled* **by this PI at** *Miami VA Medical Center*:
0

* **From the above, how many are expected to** *complete* **this study (participate in the study beyond initial enrollment)?**
0

## 5a. Study Populations

5.3. *** Study populations to be included in this study where PI will be conducting research and those sites where the UM IRB will have oversight responsibility:**

| Check all that apply | Notes |
|---|---|
| Poor/uninsured | |
| Illiterate/educationally disadvantaged | |

5.3.A. **If** *other*, **please specify:**

5.3.B. **Describe below any additional safeguards that have been included to protect vulnerable subjects:**
The study design and use of CHWs is designed to determine if our intervention is effective in poor/underserved/educationally disadvantaged Latino population. Issues of poor access, health literacy are specifically adressed as part of the CHW intervention.

## 5b. Inclusions/Exclusions

5.4. * **Is the population being enrolled in this study at high risk for incarceration?**
○ ○Yes ⊙ ⊙**No**

5.4.A. **If** *yes*, **will the subjects be withdrawn from the study once they are incarcerated?**
○ ○Yes ⊙ ⊙**No**

5.4.A.(i) **If the above answer (question 5.4.A.) is** *no*, **describe how re-contacting/re-consenting, treatment, and/or follow-up will occur:**

*NOTE: If a subject becomes incarcerated while enrolled in a study, all research interactions and interventions with that subject, and the obtaining of identifiable private information about the subject, must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol.*

*If notified that a previously enrolled research subject has become a prisoner, the principal investigator must promptly seek IRB re-review of the protocol in accordance with the requirements of subpart C if the principal investigator wishes to have the prisoner-subject continue to participate in the research. In special circumstances in which the principal investigator asserts that it is in the best interests of the*

*subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.*

5.5. * **What are the criteria for exclusion of participants from the research?**
Exclusion criteria:

a) Type 1 diabetics, as their care is quite distinct from that of Type II patients, and there are very few such patients in the ACC clinic;

b) Patients with diabetes diagnosed when under age 25 ("newonset"
Type I diabetes) as such patients are extremely rare in our primary care clinic;

c) Patients who do not selfidentify as Hispanic (Hispanics can be of any race e.g. white, black, mixed);

d) Any lifethreatening or extreme medical comorbidity,
such as an active cancer diagnosis, paraplegia, or end stage cardiopulmonary disease;

e) Having a diabetes diagnosis for < 1 year, to ensure the stability of hemoglobin A1C values above 8.0;

f) Planning to move out of the county during the next year;

g) Enrollment in any other CVD or diabetes intervention study;

h) Arm circumference of > 47 cm (oscillometric cuffs do not give accurate readings).

5.6. * **Will any population be systematically excluded in this study?**
◉ ◉ **Yes** ○ ○ No

5.6.A. **If** *yes***, provide rationale/justification for this exclusion:**
As our aim is to determine if the intrevention is effective among Latinos, non latinos will not be included in the study.

5.7. * **What are the criteria for inclusion of participants in the research?**
To be eligible for the study patients must be:

1) Adult patients age 35- 70 years

2) Receiving care at the ACC clinic (2 visits with a primary care provider in the previous year)

3) Living in Miami-Dade county (based on zip codes);

4) Had a hemoglobin A1C done within the past year, with the latest value being > 8.0;

5.8. * **Will only one group of individuals be systematically selected and recruited for this study (e.g., welfare patients, racial and/or ethnic minorities, persons confined to institutions or persons determined to be incapacitated)?**
◉ ◉ **Yes** ○ ○ No

5.8.A. **If** *yes***, please state how this participant group will benefit from the results of the research and provide the reasons and justifications to target this group:**

As reviewed, traditional approaches to CVD management among Latino Diabetics have met with limited success. CHW is a promising but as of yet unproven intervention among Latinos. Thus, our aim is to determine if the CHW intrevention is effective among Latinos. Thus, only Latinos will be included in the study. If effective, this strategy could be widely disseminated to improve CVD and diabetes care among Latino groups.

## 6. Subject Recruitment

6.1. *** From what sources or by what methods will subjects be recruited?**
Check all that apply
Primary physician/physician specialist
Outpatients/clinics

6.1.A. **If** *postings within hospital*, **please indicate name of facility:**

6.1.B. **If** *emergency room*, **please indicate name of facility:**

6.1.C. **If** *other*, **please specify:**

## 6a. Subject Recruitment (cont'd)

6.2. * **Provide a step-by-step description of the recruitment procedures used to identify and/or contact prospective participants:**
Recruitment Plan.

Our target population is adults aged 35-70 years living in Miami-Dade who are being followed at the ACC and have their last HgAIC being >8.0. We propose two alternative recruitment strategies. The study design will be presented to all the attending physicians who supervise residents at the JMH ACC General Internal Medicine Clinics in scheduled and ad hoc meetings, at which a brochure summarizing the goals and protocol will be distributed. We have already had preliminary discussions with several attendings and obtained their input regarding study design and recruitment strategies. These include a phone based strategy that uses medical records and an in person strategy during clinic visits.

Electronic Medical Records / Phone Based Strategy:
Using pre-programmed algorithms, once a month a research assistant (RA) will query the clinical data system of JMH patients seen in the last month at the JMH ACC General Internal Medicine Clinics with at least one additional prior visit in the last year (that is two visits in last year). Any patient who has had a laboratory report with their last HgAIC reading being >= 8.0 and ages 35-65 will be flagged and information entered unto VELOS. From VELOS contact information including the patients name, address and phone number will be obtained (VELOS is linked to JMH's IDX system).

Introductory letters will be sent to these patients by the RA, including a study brochure describing the study and a self- addressed stamped envelope patients could use to either accept or decline being called for participation. Interested patients will then receive an initial contact telephone call by the recruiter. In the event a patient cannot be contacted, the recruiter will make at least 5 attempts per patient at different times and days, and will maintain detailed call logs. Having reached a possible enrollee by phone, the recruiter will provide an explanation of the study, what would be required of the patient and answer any questions. If the patient is interested in participating, the recruiter will conduct a formal inclusion and exclusion screen using prepared scripts in VELOS. Pts who meet the screen will be invited to participate. If they agree to participate an appointment will then be made for eligible participants for the initial visit to the Clinical Research Center (GCRC). The appointment will occur within two weeks from the date of the screen. The recruiter will mail an appointment card reminder, another

study brochure and study instructions to participants, with a detailed map to the medical center. Reminder telephone calls will then be made 48 hours before the visit. The patient will also be reminded, by card and phone, that they need to bring all of their medications to the GCRC visit and arrive fasting as bloods will be drawn. As patients need to be fasting for their blood draws, all visits will be scheduled for the morning. To further limit the risk of hypoglycemia, patients will be asked to bring in a snack or given one at the clinic to take after their blood has been drawn and before the interview. At the GCRC visit patients will again be explained the study, have any questions or concerns they have addressed, and undergo the eligibility screen a second time. If eligible and interested in participating signed informed consent will be obtained at that time.

Recruitment during clinic visits.

Based on provider feedback, it seems that there is a strong probability that over half of all phone numbers in the JMH electronic records may be incorrect. If the phone based strategy is not meeting our recruitment goals, we will shift to an alternative approach that involves clinic based recruitment. The RA will attend several afternoon clinic sessions each week and reminds attending and all of the general medicine residents of the study and ask them to please notify him (her) if any of the patients they are seeing that they may meet the study criteria. If allowed by the provider, the recruiter will approach such patients briefly (less than two minutes) describe the study and provide a study brochure. If patients are interested in receiving more information and being potentially enrolled, contact information will be obtained from the patient and at an agreed upon time the recruiter will contact the patient by phone. The recruiter will make at least 5 attempts to reach the patient at different times and days, and will maintain detailed call logs. Once they reach the potential enrollee by phone, the recruiter will provide more detailed information about the study, what would be required of the patient and answer any questions. If the patient is interested in participating, the recruiter will conduct a formal inclusion and exclusion screen using prepared scripts and an appointment will then be made for eligible participants for the initial visit to the Clinical Research Center (GCRC). The appointment will occur within two weeks from the date of the screen. The recruiter will mail an appointment card reminder, another study brochure and study instructions to participants, with a detailed map to the medical center. Reminder telephone calls will then be made 48 hours before the visit. The patient will also be reminded, by card and phone, that they need to bring all of their medications to the GCRC visit and arrive fasting as bloods will be drawn. As patients need to be fasting for their blood draws, all visits will be scheduled for the morning. To further limit the risk of hypoglycemia, patients will be asked to bring in a snack or given one at the clinic to take after their blood has been drawn and before the interview.

6.2.A. **Please upload copies of scripts, recruiting materials, and advertisements:**

| Name | Description | Version |
|---|---|---|
| 20090751_LTR_IRBapp_Graduation_ENG.docx | | 0.03 |
| 20090751_LTR_IRBapp_Graduation_SPN.docx | | 0.05 |
| 20090751_LTR_IRBApp_Inactive_ENG.doc | | 0.01 |
| 20090751_LTR_IRBApp_PhoneDisconnected_ENG.doc | | 0.01 |
| 20090751_LTR_IRBapp091410_ Recruitment_ENG.doc | | 0.03 |
| 20090751_LTR_IRBapp091410_ Recruitment_SPN.doc | | 0.03 |
| 20090751_LTR_IRBapp091410_Control _Letter_ENG.doc | | 0.03 |
| 20090751_LTR_IRBapp091410_Control _Letter_SPN.doc | | 0.03 |
| 20090751_NFO_IRBapp_Brochure_ENG.pdf | | 0.07 |
| 20090751_NFO_IRBapp_Brochure_SPN.pdf | | 0.06 |
| 20090751_SCR_IRBapp_TelephoneScreen_ENG.doc | | 0.06 |
| 20090751_SCR_IRBapp_TelephoneScreen_SPN.doc | | 0.04 |
| Back to English Cert LTP 2013.pdf | | 0.01 |
| CARINO graduation invite back.docx | | 0.01 |
| CARINO graduation invite spanish.docx | | 0.01 |

| | |
|---|---|
| Invitation forward and back certificate.pdf | 0.01 |
| Letter to clients-Inactive status Original SPA.doc | 0.01 |
| Letter to clients-Inactive status.Eng.back TRANSLATION.docx | 0.01 |
| Letter to clients-No contact-Phone disc Original SPA Nadia12-10.doc | 0.01 |
| Letter to clients-No contact-Phone discon Eng backTRANSLATION.doc | 0.01 |
| Letters to Carino Participants for and back cert.pdf | 0.01 |

*NOTE: Any materials that will be given to or seen by potential subjects must be reviewed and approved by the IRB. This includes assessments, instruments, diaries, questionnaires, and all screening and recruitment materials, including advertisements, web postings, letters, and telephone scripts. Only IRB approved versions of these materials may be used during the course of the study.*

6.3. * **What measures will be taken during the recruitment process to safeguard against the potential coercion or the appearance of coercion of participants, particularly vulnerable populations?**
During the initial contact in the clinic and during the phone call visit patients will be carefully explained that their participation in the study is voluntary, and that their benefits and the care they receive at JMH/ UM or elsewhere will not be compromised in any way if they refuse to participate.

This information will again be stressed to potential participants during their GCRC visit prior to teir providing signed informed consent. The RA will be bilingual and all study forms, brochures and information will be provided to patients in the language of their preference (since they are Latino either English or Spanish).

6.4. * **Are there specific criteria to prematurely end a particular subject's participation in the study (e.g., predetermined safety endpoints, unexpected clinically significant findings, distress or** *serious* **adverse events, etc.)?**
Select one

- ○ Yes
- ◉ No
- ◉
- ○ Not Applicable

6.4.A. **If** *yes***, please describe:**

6.5. * **Will subjects be remunerated for their participation in the study in any way other than credit toward a course requirement?**
◉ ◉ **Yes** ○ ○ No

## 6b. Remuneration

6.5.A. *** List type, frequency, interval, and total value of remuneration:**

| | Type of Remuneration | Frequency | Total Value |
|---|---|---|---|
| View | Cash | 2 | 80 |

6.5.B. * **If a subject withdraws from the study early, will remuneration be prorated?**
no

6.5.B.(i) **If *yes*, describe plan for prorating payments and ensure that this plan is defined in consent forms:**

6.5.B.(ii) **If *no*, justify why prorated payment is not being offered:**
Patienst will receive $40 dollars during their initial visit and then $40 during their 12 month visit which is their 2nd and final visit

## 6c. Financial Liability

6.6. * **Financial Liability for Study Participants:**
Complete the table below, indicating the responsible party for payment of research activities and procedures.
☐ ☐ **Not applicable**

| Procedure or Activity | Frequency |
|---|---|

View all study related procedures

6.7. *** Select all categories indicating costs which participants or their insurance companies will be responsible for:**
Check all that apply

☑ Participants will have no costs associated with this study

☑

☐ ☐ Study-related procedures which would be done under standard care

☐ ☐ Study-related procedures not associated with standard care

☐ ☐ Administration of drugs/devices

☐ ☐ Study drugs

☐ ☐ Study devices

☐ ☐ Other

6.7.A. **If *other*, please specify:**

6.8. *** In the event of study-related subject injury, who will be responsible for compensation?**
**Other 3rd Party**

6.8.A. **If *Other 3rd Party*, please specify:**
**Or study is not a drug or device and we do not forsee any injuries related to the study. But if any occur (car accident while coming to GCRC) they will need to be covered by the patients insurance or the patient**

## 7. Informed Consent

7.1. * **Is an alteration of the consent process being requested?**
○ ○Yes ⊙ ⊙**No**

*NOTE: "Alteration of consent" is when the consent procedure does not include, or alters, some of the required elements of informed consent. This only applies to studies conducted by state or local government on public benefit or service programs. See* http://www.hhs.gov/ohrp/humansubjects/assurance/consentckls.htm

7.2. * **Is a waiver of informed consent being requested?**
○ ○Yes ⊙ ⊙**No**

*NOTE: This indicates there is no consent process; waiver criteria need to be justified.*

7.3. * **Is a waiver of signed consent being requested?**
○ ○Yes ⊙ ⊙**No**

*NOTE: This indicates that the consent process will occur, but there is no signed consent (i.e., verbal script or consent letter).*

## 7c. Informed Consent (cont'd)

7.9. * **Describe the specific steps for obtaining informed consent (e.g., by whom, his/her credentials, language, where, when, etc.):**
☐ ☐**Not applicable**
The study research assitant (a UM employee) that has completed all of her human subjects cetrtifcations and has been trained as a resaerch assistant will obtain informed consent from subjects when they present for their initial study visit or during their regular appointment time at the JMH ACC General Internal Medicine clinics.

7.10. **Consent may be required from a parent, legal guardian, legal representative, court-appointed representative, or health care surrogate where research involves children/minors, wards of the state, cognitively or developmentally impaired individuals, comatose or traumatized or emergency subjects, as well as any other subjects lacking capacity to consent. Such surrogate/representative/guardian can only consent if the IRB has approved the research under HHS or FDA regulations. For court-appointed guardians, court assent is required.**

*If your study involves any of these groups*, **please specify below whether consent will be obtained from such surrogate/representative/guardian and describe the process for obtaining such consent:**
NA

7.11. * **What protections will be offered to persons with cognitive impairment or to persons determined to be incapacitated? Describe how capacity for consent will be determined, whether cognitive capacity is expected to change significantly during the study, whether a legally authorized representative or health surrogate has been designated for purposes of obtaining informed consent, and whether court approval has been obtained (for court-appointed guardians). Describe plans to re-consent subjects after a change in the subject's cognitive capacity.**

☐ ☐**Not applicable**
All our patients will be otupetients age 35-65 years who will need to carry out a converstion and complete a phone eligibility screen. Subjects with major cognitive impairments will not be able to complete the phone screen. If the phone screen is not complete the patient will not be enrolled into

the study.

7.12. * **How will informed assent for children and parental consent/permission be obtained?**

☐ ☐ **Not applicable**

NA

7.13. * **Describe plans to re-assent or obtain consent for child subjects during the study if the subject reaches the age of majority (18 years) or if there is a significant change in cognitive capacity (i.e. gets older or regains consciousness).**

☐ ☐ **Not applicable**

NA

7.14. * **How will non-English speaking participants be consented?** *(Federal regulations require the equitable selection of minorities as research subjects to assure that they receive an equal share of the benefits of research and to ensure that they do not bear a disproportionate burden.)*

| Check one | Notes |
|---|---|
| ○ **Not Applicable** | |
| ◉ A translated written informed consent document in a language understandable to the participant | *This should be an accurate translation of the IRB-approved English version of the full informed consent document. Translations of IRB-approved informed consent documents must be made by a certified translator. Click here for list of certified translators.* |
| ○ Orally, using a qualified translator to translate the English informed consent document to the participant, and a translated short form in a language understandable to the participant. | *See IRB Policy IV.B. "Documentation of Informed Consent"* |

7.15. * **Informed Consent Document Templates**

☐ ☐ **Not applicable**

**Please attach all consent and assent templates associated with this study. (This includes genetic consent, HIV consent, tissue banking consent, etc.)**

| Name | Description | Version |
|---|---|---|
| 20090751_ICF_IRBapp_AudioVideo_ENG.doc | | 0.02 |
| 20090751_ICF_IRBapp_AudioVideo_SPN.doc | | 0.02 |
| 20090751_ICF_IRBapp_JHSMain_ENG.doc | | 0.10 |
| 20090751_ICF_IRBapp_JHSMain_SPN.doc | | 0.07 |
| 20090751_ICF_IRBapp_JHSRepository_ENG.doc | | 0.04 |
| 20090751_ICF_IRBapp_JHSRepository_SPN.doc | | 0.06 |
| 20090751_ICF_IRBapp_UMMain_ENG.doc | | 0.07 |
| 20090751_ICF_IRBapp_UMMain_SPN.doc | | 0.06 |
| 20090751_ICF_IRBapp_UMRepository_ENG.doc | | 0.04 |
| 20090751_ICF_IRBapp_UMRepository_SPN.doc | | 0.06 |

# 8. Protected Health Information

Protected health information (PHI) is individually identifiable health information that is or has been collected or maintained by the University of Miami or JHS or created for purposes of providing medical care/treatment and can be linked back to the individual participant.

8.1.(a) * **Will Protected Health Information (PHI) be accessed (used or created for treatment) *prior to contact with subjects* in this research?**
◉ **Yes** ○ No

8.1.(b) * **Will PHI be accessed (used or created for treatment) during the course of the proposed research?**
◉ **Yes** ○ No

# 8a. Protected Health Information (cont'd)

8.2. * **I am requesting or have requested a:**
Check all that apply

- ☑ Partial Waiver of Authorization
- ☐ Full Waiver of Authorization
- ☑ HIPAA Authorization from Subjects
- ☐ Limited Data Set
- ☐ Certification Preparatory to Research
- ☐ Certification for Research with Decedents' Information

# 8b. Identifiers

8.3. * **To which of the following identifiers about subjects (or their relatives, household members, or employers) might access be needed prior to the submission of the protocol and/or during the course of the proposed research?**

NOTE: When using or disclosing PHI or when requesting PHI from another covered entity, an investigator must make reasonable efforts to limit PHI to the *minimum necessary* to accomplish the intended purpose of the use, disclosure, or request; *only collect PHI essential to the study, and record as few identifiers as possible*.
Check all that apply
Names
Geographic subdivisions smaller than state (e.g., street address, city, five digit zip code, county)
Months or specific dates (e.g. birth date, admission date, month of discharge, date of death)
Telephone numbers
Medical record or prescription numbers

8.3.A. **If** *other unique identifying number, characteristic, or code***, please specify:**

## 8d. Partial Waiver

8.5. * **Has a** *partial waiver* **of HIPAA Authorization been requested and acknowledged by the HSRO prior to the submission of this protocol?**
○ ○Yes ⊙ ⊙**No**

8.5.A. **If** *yes***, upload the IRB-approved partial waiver of HIPAA authorization related to this study:**

| Name | Description | Version |
|---|---|---|
| There are no items to display | | |

**If you answered** *no* **to question 8.5, please answer the following questions:**

8.6. **Is it impracticable to conduct the proposed research** *without a partial waiver* **of authorization?**
yes

8.6.A. **Please provide a supporting explanation/information:**
The use is sought solely to review PHI as necessary to prepare for the initiation of a research protocol.

There are two potential recruitment approaches. One involves a review of electronic data (in Cerner) to identify patients been followed at the JMH ACC clinic whose AIC is above 8.0 and who meet the age eligibility. These patients will then be mailed letters and subsequently be called to determine their willingness to participate in the research study. Thus prior to any contact with the patient the study team will need information that would allow them to contact potentially eligible subjects.

In the other scenario, the study team will approach physicians and providers seeing patients in the clinic and request names of patients being seeing that day who may meet study eligibility criteria. Since the study team staff need to know the potential subjects AIC level and name prior to approaching the patients they will need to be able to access this information from physicians prior to speaking to the patients.

## 8f. Partial or Full Waiver

8.8. * **Does the use of and/or disclosure of PHI involve minimal risk?**
⊙ ⊙**Yes** ○ ○No

8.8.A. * **Provide supporting explanation/information:**
The only information that we will be obtain from Cerner is the patients name, age address, phone, and HgAIC level. This data will be collected and maintained in the VELOS system.

If subjects decline to have this information stored in VELOS (as per phone script) it will not be maintained in VELOS. The AIC without any identifiers (PHI) will be maintained to describe non participants.

8.8.B. **What are the plans to protect subject-identifying information from use and disclosure? If information will be stored in an electronic database, describe how this system will be protected from unauthorized users, and state how long the database will be kept:**
The RA will keep the data in the UM VELOS system. The data privacy protections in the UM

VELOS system was an important consideration when we chose to use this platform for data management

If subjects decline to have this information stored in VELOS (as per phone script) it will not be maintained in VELOS. The AIC without any identifiers (PHI) will be maintained to describe non participants.

8.8.C. **What are the plans to destroy the identifiers (identifiers must be destroyed at the earliest opportunity) or to return to UM or JHS subject identifying information at the conclusion of the research?**
The files linking subjects to ID numbers will be only availble through VELOS. These files will be deleted at the end of the research period.

If subjects decline to have this information stored in VELOS (as per phone script) it will not be maintained in VELOS.

8.8.D. **What written assurances have been made that the protected health information will not be reused or disclosed to any other person or entity? Describe below:**
Subjects will be told that all study records will be kept confidential to the extent allowed by law. That their personal identity will not be revealed in any publications or released with results. Also that all information will be completely confidential and shared only with subject, their providers and and with other medical personnel only with their written authorization.

8.9. * **Is it impracticable to conduct the proposed research without access to and use of subjects' PHI?**
◉ ◉ **Yes** ○ ○ No

8.9.A. * **Provide supporting explanation/information:**
We will need to know the subjects HgAIC level and name, adress and phone information in order to contact by mail and phone to describe the study and inquire if they are interested in participation.

8.9.B. **If the proposed research involves access to and analysis of existing protected health information maintained by or on behalf of the University or JHS (***i.e. it is not clinical research***), explain why use of a limited data set is not appropriate:**
We need the contact information in order to be able to contact potential enrollees to determine eligibility and potential interest in enrolling in the study.

8.10. * **What PHI will be accessed? Describe format, contents and medium containing the PHI:**
Name, address, phone number, year or birth and hemoglobin AIC.
This will be obtained from CERNER.

If subjects decline to have this information stored in VELOS (as per phone script) it will not be maintained in VELOS. The AIC without any identifiers (PHI) will be maintained to describe non participants.

8.11. * **Who will have access to the information? List individuals below:**
Study PI, project coordinator, and research assisstant

8.12. * **Will persons who have access to the information be required to sign confidentiality agreements?**
◉ ◉ **Yes** ○ ○ No

## 8g. Partial Waiver (cont'd)

8.13. * **Federal law prohibits the re-use or disclosure to a third party of any protected health information created or obtained pursuant to a partial waiver of authorization, except:**

- **as required by law;**
- **for oversight of the research;**
- **or for other research for which individual authorization or a new waiver of authorization is obtained.**

**I confirm that I agree to abide by these limitations:**
◉ ◉ **Yes** ○ ○ No

## 8i. HIPAA Authorization

You have indicated that the proposed research requires access, use, disclosure or analysis of PHI and you will be requesting authorization from the study subjects.

8.15. * **Complete and upload the HIPAA Authorization Form B:**

| Name | Description | Version |
|---|---|---|
| FormB-EnglishFillable_rev10132009.doc | | 0.02 |
| FormB-SpanishFillable_rev10132009 HIPPA.doc | | 0.01 |

8.16. **Provide supporting explanation/information, if you have made any changes to the HIPAA Form B template:**

## 11. Use of Human Biological Samples

11.1. *** List all samples to be used in this research:**

Type of sample
View we will store about 27cc of blood for potential future research.
View One set of bloods (the 8cc) will be storred and run in batches for A1C, LDL

11.2. * **Will it be possible, if so requested, to provide the participant with the sample/data for this study?**
yes

11.2.A. **If *no*, please explain:**
Yes, after 12 month, copies of their results will be provided. For the initial blood drawn we will not provide subjects with sample data. Knowing the result of A1C and LDL is part of intervention and can potentially contaminate the outcome of study. However, if the blood drawn collected is of a concerning result we will immediately notify their Primary Care Provider.

Fo rfuture studies based on data collected in repository, We will attempt to notify subjects hvaing any values on subsequent testing that are alarming or crticial.

11.3. * **Will you allow participants to request the samples/data in this study be destroyed?**
yes

11.3.A. **If *no*, please explain:**
Yes. The additional tissue will be for the research repository. The blood will be stored for up to 5 years and will be destroyed after that.

## 15. Conflict of Interest

*As the Principal Investigator, you must be aware of any conflict of interest of the protocol team or institution. Please note that the thresholds of ownership described below apply to the aggregate ownership of each individual investigator (or other key personnel, to the best of their knowledge) and their immediate family. The immediate family includes each investigator's spouse, domestic partner and dependent children (e.g., if an investigator together with his/her spouse, domestic partner and dependent children own a total of $10,000 or 5% worth of equities in the sponsor, it should be reported below).*

*"Conflicts of interest" apply to each investigator or other individuals listed as key personnel. Do not consider the combined ownership of all investigators/key personnel. Do not consider compensation for the % effort on a study.*

15.1. * **Does any person obtaining consent have any existing relationship (family, social, or professional, including physician-patient or student-teacher) with the subject(s)?**
◯ ◯Yes ⊙ ⊙**No**

15.1.A. **If *yes*, describe the relationship(s) and how subjects will be protected against undue influence or coercion:**

15.2. * **Will there be any programs, bonuses, rewards or other incentives that may be offered to this site and/or its faculty or staff by the sponsor or others for rapid enrollment?**
◯ ◯Yes ⊙ ⊙**No**

15.2.A. **If *yes*, please describe:**

*Note: Before accepting any awards, the IRB must be informed of the nature and value of these incentives.*

15.3. * **Do any of the investigators or members of their immediate families receive from the sponsoring entity salaries, consulting fees, or other compensation for services that exceed $10,000 in any twelve month period?** *(Note: if the sponsoring entity is the full time employer of the investigator, co-investigator or key personnel (i.e. UM or JHS) then answer "No." Do not consider compensation for the % effort on a study.")*
◯ ◯Yes ⊙ ⊙**No**

15.4. * **Do any of the investigators or members of their immediate families serve as an officer, director, or as a member of any advisory board with the sponsoring entity?**
◯ ◯Yes ⊙ ⊙**No**

15.5. * **Do any of the investigators or members of their immediate families have an equity interest that exceeds $10,000 in value or represents more than 5% ownership in the**

**sponsoring entity?**
○ ○Yes ⊙ ⊙**No**

15.6. * **Do any of the investigators or members of their immediate families have any intellectual property rights (patents, copyrights, royalties) in any article(s), product(s), drug(s), device(s) or other material(s) that will be involved in this research?**
○ ○Yes ⊙ ⊙**No**

15.7. * **Do any of the investigators or members of their immediate families have any other financial interest or relationship that would reasonably be affected by this research?**
○ ○Yes ⊙ ⊙**No**

15.8. * **Do any of the investigators or others know of any institutional conflict of interest pertaining to this study?**
○ ○Yes ⊙ ⊙**No**

15.8.A. **If** *yes*, **please describe:**

15.9. * **Has any of the technology used in the study been developed in whole or in part at the University of Miami?**
○ ○Yes ⊙ ⊙**No**

## 16. Monitoring Plans

16.1. * **Select the item below that most accurately reflects the plan for data and safety monitoring for this study:**

Select one

⊙ The study will be monitored only by the study investigators and/or sponsor.

⊙

○ The study will be monitored by at least one individual who is not associated with the study, but not
○ by a formally constituted Data and Safety Monitoring Board (DSMB).

○ A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.
○

○ Not applicable
○

16.2. **Has an internal (UM or JHS) data safety monitor or board/committee been established to provide additional oversight or monitoring of this study for safety and adherence to the study protocol?**
○ ○Yes ⊙ ⊙**No**

16.2.A. **If** *yes*, **describe the composition of the committee and how they will communicate findings to the IRB:**

16.3. **Has an external (non-UM or JHS) data safety monitor or board/committee been**

**established to provide additional oversight or monitoring of this study for safety and adherence to the study protocol?**

○ ○ Yes ⊙ ⊙ **No**

16.3.A. **If *yes*, describe the composition of the committee and how they will communicate findings to the IRB:**

## 17. Study Funding

17.1. *** How is the study being funded or supported?**

| Check all that apply | Description |
|---|---|
| Extramural funding (i.e. federal, state, industry sponsor, foundation, etc.) | Study will receive monetary support from outside of the University, including industry sponsor, foundation, or other funding source **OR** will receive a drug/device (with or without monetary support) |

17.2. **If study is *extramurally funded/supported*, list funding sources below:**

| | Name | Type of Funding | Pending? |
|---|---|---|---|
| View | NIH/ NHLBI | Federally-funded | no |

## 19. Attach Documentation

The documents listed below must be uploaded, as applicable to your study:

19.1. **Attach grant application(s):**

| Name | Description | Version |
|---|---|---|
| R01HL083857.pdf | | 0.01 |
| yr1progressreport.pdf | | 0.01 |

19.2. **Attach sponsor's protocol:**

| Name | Description | Version |
|---|---|---|
| There are no items to display | | |

19.3. **Attach investigator brochure:**

| Name | Description | Version |
|---|---|---|
| mhhiPbroch.pub | | 0.01 |
| PDF MHHI Brochure.pdf | | 0.01 |

19.4. **Attach clinical trial contract:**

| Name | Description | Version |
|---|---|---|
| There are no items to display | | |

***** *Please note: If this is a WIRB protocol, please go to http://www.wirb.com, complete the Initial Submission Form, and then upload it here by clicking on the Add button below. In addition, provide a hard copy of the WIRB form to the Human Subjects Research Office.*

19.5. **Upload External IRB (WIRB, FL DOH IRB)/CIRB submissions:**

| Name | Description | Version |
|---|---|---|
| There are no items to display | | |

19.6 **Attach appropriate certifications or licenses for study personnel and any other related documents:**

| Name | Description | Version |
|---|---|---|
| Amend Nov 2011 CITI.pdf | | 0.01 |
| CITI Collaborative Institutional Training Initiative_ana palacio 2012.docx | | 0.01 |
| CITI_GCP_Certificate_CuetoV.pdf | | 0.01 |
| CITI_HIPSClinicians_Certificate_CuetoV.pdf | | 0.01 |
| CITI_UMBiomedical_Certificate_CuetoV.pdf | | 0.01 |
| CITI_UMConflictofInterest_Certificate_CuetoV.pdf | | 0.01 |
| CITI_UMGroup1_Certificate_CuetoV.pdf | | 0.01 |
| CITI_UMGroup2_Certificate_CuetoV.pdf | | 0.01 |
| CITI_UMGroup4_Certificate_CuetoV.pdf | | 0.01 |
| CITI_UMIC_Certificate_CuetoV.pdf | | 0.01 |
| citiCompletionReport2187924.pdf | | 0.01 |
| Cueto_CV_current.pdf | | 0.01 |
| group 4.pdf | | 0.01 |
| o.fontan citi.pdf | | 0.01 |

## Electronic Submission Instructions

1. Each member of the protocol team must log-in to eProst and click on "**Submit Conflict of Interest"** in the protocol workspace for this particular protocol.
2. The **Principal Investigator** is the only protocol team member authorized to submit a protocol for review. To submit the protocol for review, please click the **"Submit Protocol"** activity button found under **"My Activities"** in the left-hand navigation area. *Note: If there is any missing information, eProst will prompt you to provide this before the protocol can be submitted.*
3. Execution of the "Submit Protocol" activity will move the protocol to the **"Originating Department Review"** state.
4. Once the **Originating Department** approves the protocol, it may require **"Ancillary Committee Review."**
    a. If **Ancillary Committee Review** required, the protocol state will change to "**Ancillary Committee Review."**
5. When the protocol reaches the HSRO office, the study state will reflect **"Pre-Board Review."**

# Signatures

[electronically signed by Olveen Carrasquillo on 10/5/2009]
**Principal Investigator**

**Co-Investigator**

**Faculty Advisor** *(if applicable)*

[electronically signed by Todd Erceg on 10/9/2009]
**Principal Department Chair or Division Chair**

SF GENERAL INFO -- 01-8 Key Personnel

| | | | |
|---|---|---|---|
| **Name:** | Victor Cueto | **Title:** | Resident Physician |
| **Employer:** | JHS | **Email:** | vcueto@med.miami.edu |
| **Department:** | Jackson Health System | **Division:** | |
| **Telephone:** | 305-585-5954 | **Fax:** | |
| **Address:** | Central 600-D | | |
| | Campus: | | |
| **Role in Project:** | Data analysis and/or statistics | | |
| | **If *other*, please specify:** | | |

SF GENERAL INFO -- 01-8 Key Personnel

| | | | |
|---|---|---|---|
| **Name:** | Ernesto Reyes-Arrechea | **Title:** | Community Outreach Coordinator |
| **Employer:** | | **Email:** | erarrechea@med.miami.edu |
| **Department:** | Medicine, Department of | **Division:** | General Medicine, Division of |

**Telephone:** 305-243-8893 **Fax:**
**Address:** Dominion Tower Suite 801

Campus:

**Role in Project:** Other

**If *other*, please specify:**
Community Health Worker to provide health education

SF GENERAL INFO -- 01-8 Key Personnel

**Name:** Aileen Chang **Title:** Resident
**Employer:** JHS **Email:** achang1@med.miami.edu
**Department:** Jackson Health System **Division:**
**Telephone:** 917-834-1181 **Fax:**
**Address:** quantum 3418

Campus: Medical

**Role in Project:** Data analysis and/or statistics

**If *other*, please specify:**

SF GENERAL INFO -- 01-8 Key Personnel

**Name:** Elizabeth Patberg **Title:** Student - Class of 2014
**Employer:** **Email:** epatberg@med.miami.edu
**Department:** Medical Education, Department of **Division:**
**Telephone:** 305-585-5212 **Fax:**
**Address:** Clinical Research Building 968

Campus:

**Role in Project:** Data analysis and/or statistics

**If *other*, please specify:**

SF GENERAL INFO -- 01-8 Key Personnel

| | | | |
|---|---|---|---|
| **Name:** | Natalie Ferras | **Title:** | Clinical Research Coordinator |
| **Employer:** | UM | **Email:** | NFerras@med.miami.edu |
| **Department:** | Medicine, Department of | **Division:** | General Medicine, Division of |
| **Telephone:** | 305-585-8799 | **Fax:** | |
| **Address:** | Ambulatory Care Center West 301<br>2901<br>Campus: | | |

**Role in Project:** Data analysis and/or statistics
Screening/recruitment
Responsible for consenting participants

**If *other*, please specify:**

SF GENERAL INFO -- 01-8 Key Personnel

| | | | |
|---|---|---|---|
| **Name:** | Hua Li | **Title:** | Biostatistician |
| **Employer:** | UM | **Email:** | HLi@biostat.med.miami.edu |
| **Department:** | Public Health Sciences, Department of | **Division:** | |
| **Telephone:** | (305)243-2206 | **Fax:** | |
| **Address:** | CRB 1065<br>R-669<br>Campus: Medical | | |

**Role in Project:** Data analysis and/or statistics

**If *other*, please specify:**

SF GENERAL INFO -- 01-8 Key Personnel

| | | | |
|---|---|---|---|
| **Name:** | Cynthia Lebron | **Title:** | Outreach Coordinator |
| **Employer:** | | **Email:** | CLebron@med.miami.edu |

**Department:** Medicine, Department of **Division:** General Medicine, Division of
**Telephone:** 3054393748 **Fax:**
**Address:** Clinical Research Building 989

Campus:

**Role in Project:** Other

**If *other*, please specify:**
research assistant

SF RESEARCH LOCATIONS -- 03-2-Performance Sites Engaged-List

## Performance Site "Engaged" in this Research

3.2.A. * **Name of Performance Site:**
University of Miami

3.2.A.(i) **If *Other*, please specify:**

3.2.A.(ii) **If you selected University of Miami in 3.2.A. above, please indicate all UM sites at which the protocol team will engage in protocol activities:**

| Check all that apply | Description |
|---|---|
| UMSM | University of Miami Medical Campus |
| CLRB | Clinical Research Building |

3.2.A.(ii)(a) **If *Other UM Site*, please specify:**

3.2.B. * **IRB of Record:**
Check all that apply
☑ UM (this includes Jackson Health System)
☑
☐ Other
☐

**If *Other* was selected for IRB of Record, please answer the following questions:**

3.2.B.(i) **If *Other*, please specify:**

3.2.B.(ii) **Does the site have an FWA (Federalwide Assurance)?**
○ ○ Yes ○ ○ No

3.2.B.(ii)(a) **If *yes*, enter name of FWA Holding Institution:**
UM

3.2.B.(ii)(b) **If *yes*, enter FWA Number:**

3.2.B.(iii) **IRB Approval:**

3.2.B.(iii)(a) **If *attached*, please upload IRB approval letter or Research Collaboration agreement:**

3.2.B.(iv) **Briefly describe activities at this site:**

SF RESEARCH LOCATIONS -- 03-2-Performance Sites Engaged-List

## Performance Site "Engaged" in this Research

3.2.A. * **Name of Performance Site:**
Jackson Health Systems

3.2.A.(i) **If *Other*, please specify:**

3.2.A.(ii) **If you selected University of Miami in 3.2.A. above, please indicate all UM sites at which the protocol team will engage in protocol activities:**

| Check all that apply | Description |
|---|---|
| UMSM | University of Miami Medical Campus |

3.2.A.(ii)(a) **If *Other UM Site*, please specify:**

3.2.B. * **IRB of Record:**
Check all that apply
☑ UM (this includes Jackson Health System)
☑
☐ Other
☐

**If *Other* was selected for IRB of Record, please answer the following questions:**

3.2.B.(i) **If *Other*, please specify:**

3.2.B.(ii) **Does the site have an FWA (Federalwide Assurance)?**
○ ○ Yes ○ ○ No

3.2.B.(ii)(a) **If *yes*, enter name of FWA Holding Institution:**
UM

3.2.B.(ii)(b) **If *yes*, enter FWA Number:**

3.2.B.(iii) **IRB Approval:**

3.2.B.(iii)(a) **If *attached*, please upload IRB approval letter or Research**

**Collaboration agreement:**

3.2.B.(iv) **Briefly describe activities at this site:**

SF SUBJECT RECRUITMENT - Part B -- 06-5a-Remuneration

## Type, Total Value, Interval, and Frequency of Remuneration

6.5.B.(i) * **Type of remuneration:**
Cash

6.5.B.(i).a. **If** *Transportation reimbursement*, **please specify mode of transportation:**

6.5.B.(i).b. **If** *Other*, **please specify:**

6.5.B.(ii) * **Total Value:**
80

6.5.B.(iii) * **Frequency of remuneration (how many times subjects will be remunerated):**
2

6.5.B.(iv) * **Interval of remuneration (points within the study that remuneration will be issued - i.e. first visit, last visit, etc.):**
first and last visit

SF SUBJECT RECRUITMENT - Part C -- 06-6-Financial liability

## Financial Liability for Study Participants

6.6.A. **Procedure or Activity:**
all study related procedures

6.6.B. **Frequency:**

6.6.C. **Responsible for Payment:**
Check all that apply

- [x] Sponsor
- [x]
- [ ] Investigator
- [ ]
- [ ] Department
- [ ]
- [ ] Subject
- [ ]
- [ ] Subject's private health insurance
- [ ]
- [ ] Subject's Medicare/Medicaid
- [ ]

SF HUMAN BIOLOGICAL SAMPLES -- 11-1-List samples to be used

## Human Biological Samples

11.1.A * **Please specify the type of human biological samples you will use, collect or store for this research:**
we will store about 27cc of blood for potential future research.

11.1.B **What will be purpose of storing samples?** *(if applicable)*
The purpose will be for additional research related to diabetes or cardiovascular disease. This may include inflammatory markers, C-reactive protein.

11.1.C * **Will the samples be destroyed after the study purpose is served?**
○ ○Yes ⊙ ⊙**No**

11.1.C.(i) **If *no*, for what future research purposes will these samples be stored?**
They will stored for additional research related to diabetes or cardiovascular disease. This may include inflammatory markers, C-reactive protein.

11.1.D. **How long will the samples be stored?**
5 years after blood draw

11.1.E. **Where will the samples be stored? Please state the exact physical location (site name and address):**
They will be stored in General Clinical Research Center GCRC . We have met Dr. Myles Wolf, Director of General Clinical Research Center and have made arrangements to store samples in GCRC, Room 721, Clinical Research Building 1120 NW 14th Street, Miami, FL 33136.

11.1.F. * **Will the storage or transportation of the samples place anyone at a health risk?**
○ ○Yes ⊙ ⊙**No**

11.1.F.(i) **If *yes*, please explain:**

11.1.G. * **Will the samples be stored with any protected health information?**
○ ○Yes ⊙ ⊙**No**

11.1.H. * **Sample collection method:**
Select one

○ Samples to be obtained will be limited to amounts routinely collected during clinical
○ procedures. This includes samples normally taken by Pathology for diagnostic purposes.

○ Samples will consist of additional material taken during a clinical procedure.
○

⊙ Samples will be obtained via a separate collection procedure done solely for the purposes of
⊙ this research.

11.1.I. * **How are the specimens identified when they are made available to the study team?**

| Check one | Notes |
|---|---|
| ○ No Identifier ○ | (i.e., no one can identify a subject from any information recorded for the research) |

◉ Indirect Identifier (i.e., a code which could be used by the source to identify a subject)

◉

○ Direct Identifier (i.e., subject name, address, Social Security number, medical record number, telephone number)

○ Investigator is custodian of specimens

11.1.I.(i) **If** *indirect identifier*, **does a written agreement or policy ensure that the source will not identify subjects to the researcher?**
○ ○Yes ◉ ◉**No**

*NOTE: If there is no agreement policy, the study does not qualify for an exemption.*

11.1.J. **Will results of this research or future tests be communicated to subjects?**
◉ ◉**Yes** ○ ○No

11.1.J.(i) **If** *yes*, **please explain:**
We will attempt to notify subjects hvaing any values on subsequent testing that are alarming or crticial.

11.1.K. **Will any portion of the sample be sent outside the University of Miami?**
○ ○Yes ◉ ◉**No**

**If** *yes*, **please answer the following questions:**

11.1.K.(i) **To whom will the samples be sent?**

11.1.K.(ii) **Will samples include identifiers or codes when released outside the University of Miami?**
○ ○Yes ◉ ◉**No**

11.1.K.(ii).a. **If** *yes*, **please explain:**

11.1.L. * **Do the samples already exist (collected prior to the development of this protocol)?**
○ ○Yes ◉ ◉**No**

11.1.L.(i) **If** *yes*, **when were the samples collected (i.e., from 1/1/00-6/30/02)?**

11.1.M. * **Does this research involve human cell lines and/or products made from human biological samples?**
○ ○Yes ◉ ◉**No**

11.1.M.(i) **If** *yes*, **please explain:**

11.1.N. * **Will the samples be used in connection with genetic research?**
○ ○Yes ⊙ ⊙**No**

SF HUMAN BIOLOGICAL SAMPLES -- 11-1-List samples to be used

## Human Biological Samples

11.1.A * **Please specify the type of human biological samples you will use, collect or store for this research:**
One set of bloods (the 8cc) will be storred and run in batches for A1C, LDL

11.1.B **What will be purpose of storing samples?** *(if applicable)*
To be able to measure if there were any changes in the participants' A1C and LDL after 12 months.

11.1.C * **Will the samples be destroyed after the study purpose is served?**
⊙ ⊙**Yes** ○ ○No

11.1.C.(i) **If *no*, for what future research purposes will these samples be stored?**

11.1.D. **How long will the samples be stored?**
until analyzed for AIC and LDL.

11.1.E. **Where will the samples be stored? Please state the exact physical location (site name and address):**
They will be stored in General Clinical Research Center GCRC . We have met Dr. Myles Wolf, Director of General Clinical Research Center and have made arrangements to store samples in GCRC, Room 721, Clinical Research Building 1120 NW 14th Street, Miami, FL 33136.

11.1.F. * **Will the storage or transportation of the samples place anyone at a health risk?**
○ ○Yes ⊙ ⊙**No**

11.1.F.(i) **If *yes*, please explain:**

11.1.G. * **Will the samples be stored with any protected health information?**
○ ○Yes ⊙ ⊙**No**

11.1.H. * **Sample collection method:**
Select one

○ Samples to be obtained will be limited to amounts routinely collected during clinical
○ procedures. This includes samples normally taken by Pathology for diagnostic purposes.

○ Samples will consist of additional material taken during a clinical procedure.
○

⊙ Samples will be obtained via a separate collection procedure done solely for the purposes of
⊙ this research.

11.1.I. * **How are the specimens identified when they are made available to the study team?**

| Check one | Notes |
|---|---|
| ○ No Identifier | (i.e., no one can identify a subject from any information recorded for the research) |
| ⊙ Indirect Identifier | (i.e., a code which could be used by the source to identify a subject) |
| ○ Direct Identifier | (i.e., subject name, address, Social Security number, medical record number, telephone number) |
| ○ Investigator is custodian of specimens | |

11.1.I.(i) **If *indirect identifier*, does a written agreement or policy ensure that the source will not identify subjects to the researcher?**
⊙ **Yes** ○ No

*NOTE: If there is no agreement policy, the study does not qualify for an exemption.*

11.1.J. **Will results of this research or future tests be communicated to subjects?**
⊙ **Yes** ○ No

11.1.J.(i) **If *yes*, please explain:**
After 12 month, copies of their results will be provided. For the initial blood drawn we will not provide subjects with sample data. Knowing the result of A1C and LDL is part of intervention. However, if the blood drawn collected is of a concerning result we will immediately notify their Primary Care Provider.

11.1.K. **Will any portion of the sample be sent outside the University of Miami?**
○ Yes ⊙ **No**

**If *yes*, please answer the following questions:**

11.1.K.(i) **To whom will the samples be sent?**

11.1.K.(ii) **Will samples include identifiers or codes when released outside the University of Miami?**
○ Yes ⊙ **No**

11.1.K.(ii).a. **If *yes*, please explain:**

11.1.L. * **Do the samples already exist (collected prior to the development of this protocol)?**
○ Yes ⊙ **No**

11.1.L.(i) **If *yes*, when were the samples collected (i.e., from 1/1/00-6/30/02)?**

11.1.M. * **Does this research involve human cell lines and/or products made from human**

**biological samples?**
○ ○Yes ⊙ ⊙**No**

11.1.M.(i) **If *yes*, please explain:**

11.1.N. * **Will the samples be used in connection with genetic research?**
○ ○Yes ⊙ ⊙**No**

SF STUDY FUNDING -- 17-3-Add extramural funding sources

## Extramural Funding Source

17.2.A. * **Name of Funding Source:**
NIH/ NHLBI

*NOTE: please enter only one funding source name in this box. If there is more than one funding source for this study, please click the "OK and Add Another" button at the bottom of this page to enter information for the additional funding/support sources.*

17.2.B. * **Type of Funding/Support:**

| Select one | Description |
|---|---|
| ⊙ Federally-funded | e.g. NIH, NSF, DoD, NCI, cooperative group, etc. |
| ○ State-funded | Includes funding received from Florida state or county sources, e.g. Children's Trust |
| ○ Industry-funded | Monetary support from an industry sponsor, e.g. clinical pharmaceutical company, device manufacturer, company, or industry organization |
| ○ Industry-supported | Sponsor provides drug or device **ONLY**, with no monetary support, **OR** sponsor provides study materials/data management at no cost |
| ○ Gift | |
| ○ Foundation | |

17.2.B.(i) **If you selected *Gift* or *Foundation* in question 17.2.B above, does the contract/agreement with the sponsor provide for payment of IRB fees?**
○ ○Yes ○ ○No

17.2.C. * **Application pending for the indicated funding source?**
○ ○Yes ⊙ ⊙**No**

17.2.D. **Funding Mechanism:**
Check all that apply
☑ Grant
☑
☐ Contract
☐

17.2.E. **Award #/Contract #:**